

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Evaluation the effect of Novafen prescription versus combination of Acetaminophen codeine and Ibuprofen on pain after surgical extraction of wisdom teeth

#### Protocol summary

##### Summary

objective: to determine a standard protocol for pain control after wisdom teeth surgeries. Inclusion criteria:1. age between 18-30 2. physical status ASA 1,2 Exclusion criteria:allergy and systemic diseases the randomized double blind controled clinical trial on 80 patients who reffered to kerman dental school,oral and maxillofacial surger deparment is performed in 2014 . 2 groups of 40 patients selected randomy from men and women who candidate for third molar surgery, according to date of admitting.2 groups were similar in age ,sex and difficulty of surgery.after filling the consent form and performing surgery ,one group recieved 20 tablets of novafen and placebo and another group recieved 20 tablets of acetaminophen codein and ibubrofen 200.but the patient and surgeon dont know the drug.patients recieve codes,then they complete the pain 3,6,12,24,48 hours after surgery according to VAS (visual analog scale) scales.then the data would be statically analyzed.patients can quit this study if they would not want want to follow the protocols sample size: with  $\alpha=0.05$  and  $\beta=0.1$ ,the sample size was 40 for each group interventions:analgesis drugs novafen and acetaninophen cod and ibubrofen outcome:analgesia

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014091919228N1**  
Registration date: **2014-12-19, 1393/09/28**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-12-19, 1393/09/28

#### Registrant information

##### Name

Sahand Samieirad

##### Name of organization / entity

Oral & maxillofacial surgery ward,oral & dental research center,kerman dental university, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 813 7859

##### Email address

sahand@kmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Kerman Dental and Oral disease research center, Kerman University of Medical Sciences.

#### Expected recruitment start date

2014-12-11, 1393/09/20

#### Expected recruitment end date

2015-02-20, 1393/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation the effect of Novafen prescription versus combination of Acetaminophen codeine and Ibuprofen on pain after surgical extraction of wisdom teeth

#### Public title

Evaluation the prescription effect of Novafen versus combination of Acetaminophen codeine and Ibuprofen on pain

#### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria:1. age between 18-30 2.physical status ASA 1,2 3.without analgesic use history 4.without oral and maxillofacial surgery history 5.without oral and maxillofacial trauma history 6.having one mesioangular lower third molar with pell & gregory class I ,A 7.without previous wisdom teeth surgery 8.without using alcohol and narcotics 9.without asthma history 10.without gastic ulcer and GI bleeding  
Exclusion criteria: 1.oral and maxillofacial surgery and admission history 2.having any chronic systemic or psychosomatic disease 3.having history or risk of infective endocarditis 4.having bleeding disease or using anticoagulant drugs like asorin 5.using alcohol and narcotics 6.acute local infection 7.allergy to codein or cafeine 8.pregnancy or lactating period

### **Age**

From **18 years** old to **30 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **80**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Single

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

dental and oral disease center,kerman university of medical sciences

##### **Street address**

kerman,jomhoori blv,shafa st

##### **City**

kerman

##### **Postal code**

76175

#### **Approval date**

2014-12-02, 1393/09/11

#### **Ethics committee reference number**

۲/۸ Է

## **Health conditions studied**

### 1

#### **Description of health condition studied**

impacted teeth

#### **ICD-10 code**

k01.1

#### **ICD-10 code description**

An impacted tooth is a tooth that has failed to erupt because of obstruction by another tooth.

## **Primary outcomes**

### 1

#### **Description**

analgesic type

#### **Timepoint**

each 8 hours after surgery

#### **Method of measurement**

mg dose

## **Secondary outcomes**

### 1

#### **Description**

pain

#### **Timepoint**

3,6,12,24,48 hours after surgery

#### **Method of measurement**

VAS scal

## **Intervention groups**

### 1

#### **Description**

tablet Novafen 400 mg ,each 8 hours after surgery,for 1 week (20 numbers)

#### **Category**

Treatment - Drugs

### 2

#### **Description**

tab acetaminophen codein 320 mg and ibuprofen 200 mg each 8 hours after surgery,for one week

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

kerman dental school,oral and maxillofacial surgery ward

##### **Full name of responsible person**

dr sahand samieirad

**Street address**

kerman dental university, shafa st,Kerman,Iran

**City**

kerman

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Research center,kerman university of medical sciences

**Full name of responsible person**

dr gholamreza sepehri

**Street address**

kerman,tahmaseb abad ave, jahad st,research center

**City**

kerman

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research center,kerman university of medical sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

kerman dental school,oral and maxillofacial surgery department

**Full name of responsible person**

Sahand Samieirad

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

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**Full name of responsible person**

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Assistant professor

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**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*  
**Analytic Code**  
*empty*

**Data Dictionary**  
*empty*